EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 760126 R000

Manufacturer: DYSIS Medical Limited

Address:
Gyleview House
3 Redheughs Rigg
Edinburgh
EH12 9DQ
United Kingdom

Single Registration Number: Not Available

EU Authorised Representative: DYSIS Medical SA

Address:
Leof Dimokratias 4-6
Neo Psychiko 15451
Greece

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-18** Date: **2022-08-18** Expiry Date: **2027-08-17**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Digital Colposcope	Class IIa
Specula – sterile single use	Class Is
Specula - reusable	Class Ir
Treatment pipe	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3560879	Issued

First Issued: **2022-08-18** Date: **2022-08-18** Expiry Date: **2027-08-17**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 760126 R000

Date: **2022-08-18**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire Bellshill ML4 3NJ United Kingdom	**ETO Sterilization**
Europlaz Technologies Ltd The Maltings Industrial Estate Hall Road Southminster CM0 7EQ UK	**Manufacture**
Sanmina-SCI AB Svedjevagen 12 Sjalevad 894 35 Sweden	**Design** **Manufacture**
Surtex Instruments Ltd. Kingspark Business Centre, Unit 202, 152-178 Kingston Road, New Malden KT3 3ST United Kingdom	**Manufacture**

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